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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,975

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Charles S. Henry

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EXAMINER

BALL, JOHN C

ART UNIT

PAPER NUMBER

1759

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,975	<b>Applicant(s)</b> HENRY ET AL.	
	<b>Examiner</b> J. CHRISTOPHER BALL	<b>Art Unit</b> 1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-38,43-45,53,54,65,66,70,73,74,76-80 and 85-87 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 3-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37,38,43-45,53,54,65,66,70,73,74,76-80 and 85-87 is/are rejected.
- 7) ☒ Claim(s) 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

1. This Office Action is based on the Response filed with the Office on November 19, 2010, regarding the HENRY et al. application.
2. Claims 1, 3-38, 43-45, 53, 54, 65, 66, 70, 73, 74, 76-80, and 85-87 are currently pending and claims 37, 38, 43-45, 53, 54, 65, 66, 70, 73, 74, 76-80, and 85-87 have been fully considered. Claims 1 and 3-36 are withdrawn from consideration as being drawn to non-elected inventions.

### ***Claim Objections***

3. Claim 44 is objected to because of the following informalities: Claim 44 is dependent upon claim 45, which follows, rather than precedes claim 44. According to 37 CFR 1.75(c), "[o]ne or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application"(emphasis added). Appropriate correction is required. For examination purposes claim 44 will be treated as if dependent upon claim 37.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 37, 38, 43-45, 54, 65, 66, and 78-80 are rejected under 35 U.S.C. 102(b) as being anticipated by an article by MARTIN et al. ("In-Channel Electrochemical Detection for Microchip Capillary Electrophoresis Using an Electrically Isolated Potentiostat", ANALYTICAL CHEMISTRY, vol. 74, no. 5, March 1, 2002, p. 1136-1143).

Regarding claim 37, MARTIN discloses a method of performing electrophoresis comprising:

attaching a first conductive element and a second conductive element to a microchip having at least one microfluid thereon (a carbon fiber; first sentence, first paragraph, "Chip Designs" section, p. 1138; and an auxiliary electrode; last paragraph, "Electrochemical Detection with Electrically Isolated Potentiostat" section, p. 1140) , wherein said microchip comprises:

at least one main separation channel (Figure 1) formed in a channel forming medium (PDMS; first sentence, first paragraph, "Chip Designs" section, p. 1138), said main channel containing at least one

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microfluid (second paragraph, "Electrophoresis Procedures" section, p. 1138);

at least one detecting channel containing a carbon fiber (Figure 1B) for performing electrochemical detection (Figure 3), said detecting channel being formed in said channel forming medium (PDMS; first & second sentences, first paragraph, "Chip Designs" section, p. 1138) and adjoining said main channel (Figure 1); and,

at least one reservoir (termed "the detection reservoir") containing said second conductive element to provide a reference to said first conductive element (last paragraph, "Electrochemical Detection with Electrically Isolated Potentiostat" section, p. 1140), said reservoir being formed in said channel forming medium (PDMS; first through third sentence, first paragraph, "Chip Designs" section, p. 1138) and containing waste (as a result the electrophoresis procedures outlined "Electrophoresis Procedures" section, p. 1138); and

applying continuous or pulsed amperometric detection to said microchip using said conductive elements (third sentence, first paragraph, "Shift in Half-Wave Potential" section, p. 1140),

wherein specimens within said microfluid migrate toward said first conductive wire (second paragraph, "Electrophoresis Procedures" section, p. 1138) and,

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wherein electrical contact with said carbon fiber generates a measurable signal (Figure 4A).

Regarding claim 38, MARTIN teaches the detecting channel intersects the main channel (Figure 1B).

Regarding claim 43, MARTIN teaches the channel forming medium comprises a polymeric material, in the form of PDMS (first paragraph, "Chip Designs" section, p. 1138).

Regarding claim 44, MARTIN teaches the channel forming medium comprises poly(dimethylsiloxane) (first paragraph, "Chip Designs" section, p. 1138).

Regarding claim 45, MARTIN teaches the first conductive element is a carbon fiber (first sentence, first paragraph, "Chip Designs" section, p. 1138) and the second conductive element is a platinum auxiliary electrode (last paragraph, "Electrochemical Detection with Electrically Isolated Potentiostat" section, p. 1140).

Regarding claim 54, MARTIN teaches the specimen comprises catechol (first and second sentences, "Electrophoresis Procedures" section, p. 1138), which is an alcohol.

Regarding claim 65, MARTIN teaches an electrical potential across the microchip to provide separation (second paragraph, "Electrophoresis Procedures" section, p. 1138) and detection of at least one specimen in the microfluid (Figure 4A).

Regarding claim 66, MARTIN teaches 33 mm and 43 mm effective separation lengths (fifth sentence, first paragraph, "Chip Designs" section, p. 1138) utilizing an electric field strength for separation of 300 V/cm (second sentence, second paragraph, "Electrophoresis Procedures" section, p. 1138), and a 54 mm effective separation lengths (fifth sentence, first paragraph, "Chip Designs" section, p. 1138) utilizing an electric field strength for separation of 100 V/cm (second sentence, second paragraph, "Electrophoresis Procedures" section, p. 1138). This leads to an applied electric potential for separating the specimens in the range from 540 V to 1290 V.

Regarding claims 78-80, MARTIN teaches including in the microfluid an electrolyte solution in the form of borate, at a pH of 9.2, which is approximately a

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pH of 9.45 (fifth sentence, first paragraph, "Electrophoresis Procedures" section, p. 1138).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 53, 70, 73, 74, 76, 77, and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over an article by MARTIN et al. ("In-Channel Electrochemical Detection for Microchip Capillary Electrophoresis Using an Electrically Isolated Potentiostat", ANALYTICAL CHEMISTRY, vol. 74, no. 5, March 1, 2002, p. 1136-1143).



Regarding claim 53, MARTIN teaches the limitations of claim 37, as outlined above.

MARTIN teaches a single detecting channel (Figure 1B).

MARTIN does not explicitly teach a plurality of detecting channels.

However, it has been held that mere duplication of parts has no patentable significance unless a new and unexpected result is produced (*In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

Regarding claims 70, 73, 76 and 77, MARTIN teaches the limitations of claims 37 and 65, as outlined above.

MARTIN teaches applied electric potential for separating the specimens in the range from 540 V to 1290 V (derived from: fifth sentence, first paragraph, "Chip Designs" section, p. 1138; and second sentence, second paragraph, "Electrophoresis Procedures" section, p. 1138), and this range is presumably the "high voltage" utilized during injection (fourth sentence, second paragraph, "Electrophoresis Procedures" section, p. 1138).

MARTIN does not explicitly teach the ranges recited in claims 70, 73, 76 and 77.

However, the separation voltage and injection voltage would be recognized by one of skill in the art as result-effective variables, and as such, would have been varied during routine operation of the method of MARTIN to include voltages within the ranges of those cited in claims 70, 73, 76 and 77.

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Regarding claim 74, MARTIN teaches the injection step is performed for 1 second (fourth sentence, second paragraph, "Electrophoresis Procedures" section, p. 1138).

Regarding claims 85-87, MARTIN teaches the limitations of claims 37 and 54, as outlined above.

MARTIN does not explicitly teach the specimen comprises glycosylated hemoglobin, hemocysteine, or uric acid.

However, given the general nature of the disclosure of MARTIN, one of ordinary skill in the art would expect successful use of the teachings of MARTIN to be applicable to any other electroactive analytes, including those recited in instant claims 85-87.

### ***Response to Arguments***

9. Applicant's arguments filed November 19, 2010, have been fully considered but they are not persuasive. Applicant argues that MARTIN fails to teach every limitation of the independent claim 37. Specifically, it is asserted that MARTIN does not teach "a microchip comprising a separation channel and a detection channel formed in the same channel forming medium" (Remarks, p. 10; emphasis in the original). It is believed that the Applicant equates the channel forming medium as a single planar substrate, which is further asserted in the

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contrasting figures present in the filed Remarks (p. 12). However, this is not the interpretation utilized by the Examiner during examination for the limitation "channel forming medium". The Applicant's original disclosure explicitly defines the term "channel forming medium" on page 8 of the specification as follows:

[0029] For the purposes of the present invention, the term "channel forming medium" refers to one or more material from which channels are formed for a microchip. The channels may be formed by impression, molding, etching, etc.

Since MARTIN teaches that the separation channel and the detection channel are both formed in PDMS, they are formed from the same material or "channel forming medium". The fact that the separation and detection channels are not in the same substrate of MARTIN is not material to the claims, as the claims do not require this limitation. Further, an argument can not be made that the specification supports that a "channel forming medium" solely and exclusively refers to a singular base, substrate, or planar unit. Therefore, the rejections based on MARTIN are maintained and all pending claims are rejected.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCB

01/28/2011

/Ula C Ruddock/  
Supervisory Patent Examiner, Art Unit 1729